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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,250	05/21/1999	ELSA AFRA, JULIA, MARIA GOULMY	2799/58994	9675

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EXAMINER	
SOUAYA, JEHANNE E	30
ART UNIT	**PAPER NUMBER**
1634	30

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/269,250	GOULMY, ELSA AFRA, JULIA, MARIA	
	Examiner	Art Unit	
	Jehanne E Souaya	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *18 and 19* is/are withdrawn from consideration.

5)☒ Claim(s) *2* is/are allowed.

6)☒ Claim(s) *1,3-17 and 20-22* is/are rejected.

7)☒ Claim(s) *1, 11-12, and 15-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/4/2002 has been entered.

2. Currently, claims 1-17 and 20-22 are under consideration in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is NON-Final.

Claim Objections

3. Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claims fail the infringement test. See MPEP 608.01(n). For example, the kit of claim 15 can be separately infringed from the method of claim 1 as claim 1 does not recite any primers. Further, the structure of the nucleic acids cannot

be determined from the recitation of claims 1 or 3, and thus the nucleic acids of claim 15 can be separately infringed from the method of claim 1 or claim 3.

Claims 11 and 12 are improperly dependent from claim 1. These claims fail the infringement test as the nucleic acids of claims 11 and 12 can be separately infringed from the method of claim 1.

Claim 16 and 17 are improperly dependent from claim 10. These claims fail the infringement test because the nucleic acids of claims 16 and 17 can be separately infringed from the method of claim 10. Claim 10 states "a primer... and/or a probe", therefore, claim 10 does not necessarily stipulate a primer. Further, the structure of the nucleic acids cannot be determined from the recitation of claims 7 or 1, and thus the nucleic acids of claim 16 and 17 can be separately infringed from the methods of claim 7 or 1.

Claim 1 is objected to. The recitation of "HA-1 ll" appears to be in error. The correct recitation should be HA-1 H.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3-17, and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to typing alleles of the minor histocompatibility antigen HA-1 comprising detecting polymorphic nucleotides in the cDNA or genomic nucleic acids of the alleles. However, the specification does not provide sufficient written description as to the sequence of the HA-1 antigen, or the cDNA or genomic DNA that encodes the full HA-1 antigen. The specification teaches allele typing of the HA-1 peptide, which is disclosed as SEQ ID NO 17. Two alleles are present resulting from a sequence change at nucleotide position 8 of SEQ ID NO 17 (nucleic acid sequence that encodes the HA-1 peptide), the "R" allele (SEQ ID NO 17) and the "H" allele (SEQ ID NO 19) corresponding to an Arginine or a Histidine at the 3rd position of the HA-1 nonapeptide (VLXDDLLEA, where X is either arginine or histidine). The specification teaches that typing these two alleles is important in typing potential donors for bone marrow transplants to prevent Graft versus Host Disease (GVHD), as patients, from two families, receiving bone marrow transplants from HLA identical donors within the family were found to develop GVHD. The specification teaches that allele typing of the HA-1 nonapeptide showed that donors and recipients differed in the HA-1 allele (p 21, example 1). The specification teaches the skilled artisan how to type the "H" or the "R" allele in a subject using the probes and primers disclosed, as well as the partial exon a and exon b sequences shown in figure 11, and the partial intron a sequence of SEQ ID NO 1. The specification teaches the sequence of the HA-1 peptide (SEQ ID NO 17 or 19) (see figure 5, p. 5-6). However, the claimed methods, products, and kits, encompass using genomic and cDNA sequences that have not been taught or described in the specification. The specification teaches that the HA-1 peptide is encoded by 2 exons from the KIAA0223 gene (p 6 and 7), and teaches a partial sequence (p. 6) of the intron located between these two exons (SEQ ID NO 1). The specification, however does

not teach the full sequence of the HA-1 antigen, nor does the specification teach the cDNA or genomic DNA that corresponds to the nucleic acid sequences that encode the antigen. The specification teaches that the KIAA0223 gene encodes the HA-1 antigen, but does not disclose what sequences within the KIAA0223 gene correspond to the HA-1 gene. It cannot be determined from the disclosure in the specification if the gene product of the KIAA0223 gene is the HA-1 antigen, wherein the HA-1 peptide is a peptide located within the HA-1 antigen (The specification does not teach that the KIAA0223 gene is the HA-1 gene) or whether the complete sequence of the HA-1 antigen is the HA-1 nonapeptide (SEQ ID NOS 17 or 19) as the specification states that The GvHD associated mH antigen HA-1 is a nonapeptide derived from the di allelic KIAA0223 gene (p. 21). Claim 1, as amended is still drawn to typing unidentified alleles because the recitation of "wherein said polymorphic nucleotides are detected *in a region of said allele corresponding* to SEQ ID NO 17 or SEQ ID NO 19" is not limited to typing alleles in SEQ ID NO 17 or SEQ ID NO 19 only. As the claims (all claims depending from claim 1) are drawn to typing unidentified alleles in undisclosed sequences, and the specification does not adequately describe the breadth of these undisclosed sequences, each of the claimed inventions is a genus for which a representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. Further, with respect to claims, 4, 5, 7-9, 11-13, 15, and 20-22, the claims are drawn to nucleic acid sequences or methods using nucleic acid sequences that can be located outside of the disclosed partial exon a, intron a, and exon b, sequences disclosed in the specification. Such sequences encompass undisclosed genomic and cDNA sequences. As set forth by the Court in Vas Cath Inc. V. Mahurkar, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable

clarity" that as of the filing date applicant was in possession of the claimed invention. Absent a written description disclosing the full sequence of the HA-1 antigen (if the HA-1 peptide does not represent the full sequence of the HA-1 antigen) or the sequences of the KIAA0223 gene that correspond to the cDNA or genomic sequences that encode the HA-1 antigen, the specification fails to show that applicant was, in fact, "in possession of the claimed invention" at the time the application for patent was filed.

With regard to claims 13, and 20-22, the claims are broadly drawn to isolated nucleic acid sequences displaying "80% sequence homology" to SEQ ID NO 1, 17 or 19 or any fragment that can be used for HA-1 typing. Many sequences are encompassed by applicant's claims, and particularly those having "80 % sequence homology" or any fragment of such would bear little resemblance to the single HA-1 peptide (VLXDDLLEA) and partial intronic sequence (SEQ ID NO 1) taught in the specification. Further, as stated above, these claims encompass undisclosed genomic and cDNA sequences that have not been taught or described in the specification. Neither the claims nor the specification set forth any structural or functional characteristics that a skilled artisan could use to identify such polynucleotides other than by SEQ ID NO. Further, the claims encompasses undisclosed sequences including genomic sequences, and a large number of variants, mutants, and homologs of SEQ ID NOS 1, 17, and 19 that have not been taught or described in the specification. Each of the claimed inventions is a genus for which a representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was

in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the disclosed SEQ ID NOS, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Accordingly, the specification does not provide a written description of the invention of claims 1, 3-17, and 20-22.

Response to Arguments

The response traverses the rejection. The response asserts that the claims have been amended to overcome the examiner's concerns. The amendments have been thoroughly reviewed but do not place the applicant in condition for allowance. Claim 1, as it is written, encompasses typing alleles outside of SEQ ID NO 17 and 19 due to the recitation of "in a region of said allele corresponding to SEQ ID NO 17 and 19". The recitation of "region" encompasses sequences on either side of SEQ ID NO 17 and 19, of unlimited length. The specification fails to show that applicant was "in possession" of these undisclosed essential sequences. Consequently, since a description of the sequences is lacking, a description of typing alleles to these undisclosed sequences is also lacking. The claims are drawn to methods of detecting undisclosed variations in undisclosed sequences.

With regard to claim 11, 12, and 14, the claims are not drawn to any specific sequence and are drawn to sequences for use in a method that uses undisclosed sequences. For example, it is unclear how the skilled artisan would be able to determine the sequence of a primer if the target sequence (in other words, the sequence it hybridizes to) is not disclosed, other than by SEQ ID NO. Such a recitation is essential in determining the specific sequence of a primer or a probe. With regard to such, it is noted that the art does not teach the skilled artisan what the exact sequence of a primer is if the sequence it hybridizes to is unknown. Further, claims 11 and 12 only recite "a [primer or probe] for use in a method according to claim..." No structural language is presented in the claims such that a correlation can be made with regard to the use of

such oligonucleotides in a method "for typing of alleles of the Minor Histocompatibility Antigen HA-1". Secondly, while the specification discloses some specific sequences that can be used in the method of claim 1, such sequences are not representative of the large genus of alleles and sequences encompassed by the claimed invention. Lack of description for claims 13 and 20-22 have been discussed in the rejection above. The response asserts that such sequences can be used to detect HA-1 H or R. This argument has been thoroughly reviewed but was not found persuasive. The comprising language in the claims encompasses sequences that are larger than any of the disclosed sequences, which reads on undisclosed genomic and cDNA sequences. With regard to % homology language, the claims encompass sequences mutants, variants and homologs that have not been taught or described. Further, such sequences would not be specific for detecting HA1 H or R alleles.

Indefinite

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, and 3-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 is indefinite in the recitation of "are detected in a region of said allele corresponding to SEQ ID NO 17 or 19". It is unclear whether the claim only encompasses typing the HA-1 H or the HA-1 R alleles, or whether the claim is drawn to detecting other

polymorphic nucleotides in SEQ ID NO 17 or 19, or whether the claim is drawn to detecting polymorphic nucleotides in a "region" outside of SEQ ID NO 17 or 19.

B) Claim 4 lacks sufficient antecedent basis for the recitation of "said at least one pair of primers". The phrase "at least one pair of primers" does not occur previously in claim 4 or in claim 1.

C) Claim 5 is indefinite in the recitation of "said 3' primer" as it is unclear if the "primer" being referred to is the 3' primer designated in claim 4, or the 3' primer designated in claim 5 (it is noted that each of these 3' primers appear to be different).

D) Claim 6 lacks sufficient antecedent basis for the recitation of "the primers". Primers are not recited previously in claim 6 or in claim 1.

E) Claim 9 is indefinite in the recitation of "position 8 or at positions 4 and/or 8" as it is unclear if the probe hybridizes to position 8, position 4, or positions 4 and 8. the recitation of "or" does not make sense because if this alternative were used, the claim would read "position 8 or position 8".

F) Claims 11, 12, and 15-17 are indefinite. With regard to claims 11 and 15, the structure of the primer cannot be determined because claim 1 does not recite a primer. With regard to claims 16 and 17, the claims recite the phrase "a primer according to claim 10", however, claim 10 could be read to lack a primer and only stipulate the structure of a probe. In such case, it is unclear what the structure of the primers of claims 16 and 17 would be. Further, the structure of the nucleic acids of claim 11, 12, and 15 cannot be determined as these claims are drawn to products which are dependent on method claims that do not set forth any structure for the claimed products.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 11-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Levi et al (Journal of the American Society for Horticultural Science; vol. 112, no:1, pp 74-78, abstract and sequence provided).

Levi et al teach a sequence (a 10 mer) that has 80% identity to SEQ ID NO 19. The intended use for the primer and probe of claims 11-12 is given no patentable weight. Further, it noted that such sequences possess enough identity to the disclosed SEQ ID NO 19 so as to be able to hybridize to the complement of SEQ ID NO 19.

10. Claims 11-13 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Noble et al (Drug Development Research, vol. 34, 1995, pp 184-195, abstract and sequence provided).

Noble teaches a sequence (a 12 mer) that possesses 83% identity to SEQ ID NO 17. The intended use for the products of claims 11-13 have been given no patentable weight. Further, it noted that such sequences possess enough identity to the disclosed SEQ ID NO 17 so as to be able to hybridize to the complement of SEQ ID NO 17.

11. Claims 13 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Levi et al.

Levi et al teach a sequence (a 10 mer) that has 80% identity to SEQ ID NO 19. The intended use for the polynucleic acid of claim 13 is given no patentable weight. Further, it noted that such sequences possess enough identity to the disclosed SEQ ID NO 19 so as to be able to hybridize to the complement of SEQ ID NO 19. The exact sequence of SEQ ID NO 19 was not disclosed in EP 97202303. Further, the EP 97202303 document does not teach or suggest truncating the disclosed sequences to arrive at the sequence of SEQ ID NO 19, therefore claims reciting such have an effective filing date of June 2, 1998.

12. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5,474,796 (12/12/1995).

Brennan teaches arrays of trimers (see Figs 1a-1c). for example, the trimer TTG is found in SEQ ID NOS 17 and 19 (positions 20-22), and such is considered a fragment of such. The term fragment has been given no length limitation. It is further noted that Brennan teaches making an array of all possible 10mers (see column 9).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levi et al or in the alternative Noble et al, each in view of Ahern (The Scientist, vol. 9, #15, 1995, from the internet, pages 1-5).

Noble et al teaches a sequence (a 12 mer) that possesses 83% identity to SEQ ID NO 17. The intended use for the kits and the products contained in such have been given no patentable weight. Further, it noted that such sequences possess enough identity to the disclosed SEQ ID NO 17 so as to be able to hybridize to the complement of SEQ ID NO 17.

Levi et al teach a sequence (a 10 mer) that has 80% identity to SEQ ID NO 19. The intended use for the kits and the products contained in such have been given no patentable weight. Further, it noted that such sequences possess enough identity to the disclosed SEQ ID NO 19 so as to be able to hybridize to the complement of SEQ ID NO 19.

Neither Noble et al nor Levi et al teach the sequences in kit format. However, Ahern teaches that providing premade biochemicals and reagents in kit format saves researchers time and are convenient. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to provide the sequences of Noble or Levi in kit format for the obvious improvement of having such in premade format to offer researchers the convenience of and the time saving effect of not having to synthesize such themselves.

Conclusion

16. Claim 2 is free of the cited prior art.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Patent examiner
Art Unit 1634
Jehanne Souaya
3/24/03